K133115

FEB 2 7 2014

6 510(K) SUMMARY

6.1 APPLICANT INFORMATION

Abbott Medical Optics Inc. (AMO) is submitting an Abbreviated 510(k) premarket notification for the COMPACT INTUITIV System. This 510(k) Summary is being submitted in accordance with the Medical Device Amendments of 1976, the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92.

Submitter Information:

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Date of 510(k) Summary Preparation: September 27, 2013

Subject Device:

Trade/Proprietary Name:	COMPACT INTUITIV System
Common Name:	Cataract Extraction System or Phacoemulsification System
Classification Name:	Phacofragmentation System per 21 CFR 886.4670
Product Code:	HQC
Regulatory Class:	II

6.2 SUBSTANTIAL EQUIVALENCE SUMMARY

The COMPACT INTUITIV System is a new phacoemulsification system designed for use in the surgical setting for ophthalmologists with experience as phacoemulsification surgeons to emulsify and remove a cataractous lens from the eye. The COMPACT INTUITIV surgical system consists of a system console that powers and operates the device, a wireless remote control, a programmable four-button foot pedal, and a sterile single-use fluidics pack. The COMPACT INTUITIV System console and its components are substantially equivalent to the console and accessories of AMO's SOVEREIGN Compact Phacoemulsification System cleared on December 29, 2011 (K111446), and the fluidics pack is substantially equivalent to AMO's SOVEREIGN Compact Disposable Tubing Set cleared on May 19, 1998 (K981116).

The devices to which substantial equivalence of the COMPACT INTUITIV System and its accessories are claimed are listed below.

Predicate Devices to which Substantial Equivalence is claimed for the COMPACT INTUITIV System and its Components/Accessories

510(k) Number	Date of FDA Clearance	Predicate Device/Accessory Name	510(k) Holder
COMPACT INTUITIV System Console			
K111446	12/29/2011	SOVEREIGN Compact Phacoemulsification System *Primary Predicate Device*	Abbott Medical Optics Inc.
COMPACT INTUITIV Wireless Remote Control			
K111446	12/29/2011	Wired Remote Control *An accessory to The SOVEREIGN Compact Phacoemulsification System*	Abbott Medical Optics Inc.
COMPACT INTUITIV Four-Button Foot Pedal			
K111446	12/29/2011	SOVEREIGN COMPACT Open-Toe Foot Pedal *An accessory to The SOVEREIGN Compact Phacoemulsification System*	Abbott Medical Optics Inc.
COMPACT INTUITIV Single-Use Pack, OPO80			
K981116	5/19/1998	SOVEREIGN Compact Disposable Tubing Set, Model OPO61 *An accessory to The SOVEREIGN Compact Phacoemulsification System*	Abbott Medical Optics Inc.

6.3 DEVICE DESCRIPTION

The COMPACT INTUITIV System is a modular ophthalmic microsurgical system that is intended for use in anterior segment (cataract) surgery. The device is used to emulsify and extract a cataractous lens. The system has the same surgical functionality and software features found in the primary predicate device, the SOVEREIGN Compact Phacoemulsification System (K111446) cleared on December 29, 2011. Like the predicate, the COMPACT INTUITIV is a mid-tier peristaltic system with a user-friendly interface that has updated technology and hardware to meet current electrical and material safety standards. The COMPACT INTUITIV consists of the **System Console**, the **Wireless Remote Control**, the **Four-Button Foot Pedal**, and the **Single-Use Fluidics Pack, Model OPO80**.

6.4 TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE

The main technological characteristics of the COMPACT INTUITIV System include ultrasonic phacoemulsification (phaco), diathermy, irrigation and aspiration, and vitrectomy. All main performance functions of the COMPACT INTUITIV System and fluidics pack, Model OPO80 are also available with the AMO SOVEREIGN Compact System predicate device (K111446) and the SOVEREIGN Compact Disposable Tubing Set, Model OPO61 (K981116).

The software modes, basic scientific concepts, energy source, compact design, intended use and FDA-recognized standards used for performance testing of The COMPACT INTUITIV System are identical to those of The SOVEREIGN Compact Phacoemulsification System (K111446). The intended use of the COMPACT INTUITIV System and its components is anterior segment ophthalmic surgery, which is the same intended use as the primary predicate device.

6.5 INDICATIONS FOR USE

The Indications for Use statement of the COMPACT INTUITIV System is the following:

The COMPACT INTUITIV System is an AC-powered device with a fragmenting needle for cataract surgery to disrupt a cataract with ultrasound and extract the cataract.

The Indications for Use statement of the Single-Use Fluidics Pack, Model OPO80 is the following:

The Single-Use Pack is used with the COMPACT INTUITIV System. The Single-Use Pack is sterilized using Ethylene Oxide and is designed for single use only

6.6 SUMMARY OF NON-CLINICAL TESTS

The COMPACT INTUITIV System has undergone design verification and validation testing including electromechanical safety testing (IEC testing) and is in compliance with the applicable requirements of safety standards. The COMPACT INTUITIV System, its components and compatible accessories were tested and found to perform as safely and as effectively as the SOVEREIGN Compact Phacoemulsification System (K111446) primary predicate device and the SOVEREIGN Compact Disposable Tubing Set, Model OPO61 (K981116). Testing of all anterior segment ophthalmic surgery modes, including phacoemulsification, diathermy, irrigation/aspiration, and vitrectomy, was conducted; all tests passed and all acceptance criteria were met. Therefore, the COMPACT INTUITIV System and the predicate devices have similar safety, effectiveness, and performance profiles.

The COMPACT INTUITIV System and its components were devèloped and tested for AMO requirements and specifications in accordance with the following FDA-recognized consensus standards:

Standard Number	Standard Title
ANSI/AAMI/ES 60601-1:2005	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN/IEC 60601-1-2:2007	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-2-2:2009	Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
IEC 62366: 2007	Medical devices – Application of usability engineering to medical devices
ISO 14971: 2007	Medical devices – Application of risk management to medical devices

Components of the Single-Use Fluidics Pack, Model OPO80, have indirect contact with the patient by providing a fluid path for sterile Balanced Salt Solution (BSS) to enter the eye during surgery. Verification and validation testing was completed and all acceptance criteria were met, demonstrating that the OPO80 Pack has a similar safety, effectiveness and performance profile as the predicate device. Biocompatibility and sterilization evaluations of the materials that make up the patient fluid path were performed to the following standards:

Standard Number	Standard Title
ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
AAMI/ANSI/ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-7:2008	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 10993-12:2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
EN/ISO 11135-1:2007	Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
ISO 11979-5:2006	Ophthalmic implants – intraocular lenses – Part 5: Biocompatibility

All materials coming into direct contact with the patient, which include handpiece needles, irrigation sleeves and tips, are the same as those used with the predicate device, have been cleared in previous 510(k) filings and are not within the scope of this premarket notification.

6.7 SUMMARY OF CLINICAL TESTS

No clinical studies were deemed necessary to determine the safety and effectiveness of the COMPACT INTUITIV System and its accessories.

6.8 CONCLUSIONS

The technological characteristics that determine the functionality and performance of the COMPACT INTUITIV System are believed to be substantially equivalent to those cleared for the SOVEREIGN Compact Phacoemulsification System predicate device, (K111446) for anterior segment (cataract) surgery and the SOVEREIGN Compact Disposable Tubing Set, Model OPO61 (K981116). The COMPACT INTUITIV System will be manufactured in compliance with FDA and ISO quality system requirements. The data from the non-clinical tests demonstrate that the device is as safe and as effective and performs as safely and as effectively as the legally marketed predicate devices. Verification and validation testing demonstrate that the functional requirements and system specifications will be met prior to commercial release.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 27, 2014

Abbot Medical Optics, Inc.
c/o Rosanne Yetemian, Ph.D., MSRS, RAC
Manager, Regulatory Affairs
1700 E. St. Andrew Place
Santa Ana, CA 92705

Re: K133115
Trade/Device Name: Compact intuitiv; System, wireless remote control, four-button foot pedal, single-use fluidics pack
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC
Dated: January 17, 2014
Received: January 22, 2014

Dear Dr. Yetemian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133115

Device Name: COMPACT INTUITIV System

Indications for Use:
The COMPACT INTUITIV System is an AC-powered device with a fragmenting needle for cataract surgery to disrupt a cataract with ultrasound and extract the cataract.

The Single-Use Pack is used with the COMPACT INTUITIV System. The Single-Use Pack is sterilized using Ethylene Oxide and is designed for single use only.

Prescription Use _X____ AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE

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